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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,740	12/05/2001	Alexander MacGregor	23936-176	2553

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
12/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
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Office Action Summary	Application No.	Applicant(s)	
	10/006,740	MACGREGOR, ALEXANDER	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 9/06/07. Claims 1, 3-8, 10-12, 14-32, 34, 35 and 37-46 are canceled. New claims 47-74 added and are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 55 and 69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description.

Claims 55 and 69 recite "hydrosoluble polymers" while the specification merely mentions hydrosoluble in paragraphs [0125] and [0130] without identifying any polymers that are useable in the invention as hydrosoluble/water soluble polymers

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 47, 50-53 and 56-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Dresdner, Jr. et al. (US 5,357,636).

Dresdner, Jr. discloses antiseptic composition comprising antiseptic agents such as povidone iodine, sodium hypochlorite, nonoxynol 9 and chlorhexidine gluconate, sodium dichloroisocyanurate, sodium perborate, to name a few (abstract; column 12, lines 50-67; column 27, lines 39-53; column 27, lines 40-50), surfactant (column 13, line 1), antibiotics (column 27, line 65 to column 28), bicarbonate or peroxide (column 30, line 51 to column 31 line 41), viscosity modifying polymer/agent such as cross-linked polyvinylpyrrolidone and carbopol (column 35, line 56 to column 36 line 37). The cross-linked polyvinylpyrrolidone is the hydrostatic pressure-modulating agent of the claims 47 and 56. Carbopol is cross-linked with allylsucrose or allylpentaerythritol and is the cross-linked hydrodynamic fluid imbibing polymer of claims 47 and 56. Sodium perborate is the expansion source of claims 56 and also meets claims 57 and 59 as the oxygen precursor source. Please note that Dresdner does not describe borate as being wet. The hypochlorite meets the limitation of chlorine dioxide source of claims 57 and 60. The antiseptic composition of Dresdner is in a non-liquid form such as a dry solid, dry powder, a paste, a foam, a gel, a coating, a solid layer (abstract; column 1, lines 15-17; column 20, line 35; column 25, lines 42, 43; column 27, line 2; column 30, lines 20-23; column 35, lines 52-55; column 39, line 12; column 64, lines 49 and 54) with the powder or dry powder or solid layer or paste meeting the limitation for compressed homogeneous mixture of claims 47 and 56 or the compressed homogeneous mixture of claims 47 and 56 read on the powdered solid

non-liquid composition of Dresdner. The release kinetics of zero order is independent of the concentration of the reactants that would be released and it is ultimately a property/characteristic of the dosage form so that it would be inherent that the non-liquid antiseptic composition of Dresdner would exhibit zero order kinetics for the release of the agent. Claims 51-53 recite the properties/characteristic of the delivery system of the dosage form. The carbonate of this reference is a carbonate source and thus meets the limitation of claim 58; specifically ammonium carbonate is named (column 30, line 54) meeting claim 58. The antimicrobial of claim 50 broadly reads on the antiseptic of Dresdner. The teaching of Dresdner, Jr. meets the limitations of the claims.

Response to Arguments

5. Applicant's arguments filed 09/06/07 have been fully considered but they are not persuasive.

Applicant argues that Dresdner does not disclose a dosage form for oral administration that includes a compressed homogeneous mixture because the flexible glove of Dresdner cannot be compressed without rendering the glove unsuitable for its intended use.

Response:

Dresdner discloses antiseptic composition in non-liquid form, such as dry solid, with the composition comprising CARBOPOL 934 (allylsucrose or allylpentaerythritol cross-linked acrylic polymer) or cross-linked polyvinylpyrrolidone or mixture thereof. The CARBOPOL and the cross-linked polyvinyl pyrrolidone and the antiseptic active agent and percarbonate or sodium perborate monohydrate or anhydrous sodium perborate make up the hydrostatic delivery system as claimed in claims 47 and 56. The non-liquid composition of Dresdner that is a

powder or solid or paste or solid layer is contained in the glove so that it is that composition that is compressible/compressed and not the glove that serves to hold the composition. Therefore, the compressed homogeneous mixture reads on the solid powder/paste/layer Dresdner. The cross-linked polyvinylpyrrolidone is the hydrostatic pressure-modulating agent of the claims 47 and 56. Carbopol is cross-linked with allylsucrose or allylpentaerythritol and is the cross-linked hydrodynamic fluid imbibing polymer of claims 47 and 56. Sodium perborate is the expansion and oxygen precursor source of claims 57 and 59.

6. Claims 47, 49-55 and 61-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Bai (US 5,840,329).

Bai discloses a dosage form in the tablet or capsule form that comprises dextran (column 3, line 52; column 7, line 24; claims 1, 4, 13 and 15), which is hydrodynamic fluid-imbibing polymer recited in claim 37 b) i), and claims 47, 54 and 61; cross-linked polyvinylpyrrolidone (column 8, lines 16, 17; claims 1, 4, 13 and 15), which is hydrostatic pressure modulating agent of claims 47, 54, 61; and active medicament (column 5, lines 6-17; column 6, line 7; column 10, lines 10-67; column 13, lines 1-11) meeting the active agent component of claims 47, 50, 61, 64. The compressed homogeneous mixture of claims 47 and 54 reads on the tablet of Bai. Claims 51-53, 65 and 66 recite the properties/characteristic of the composition of claims 47 and 61 and the composition of Bai is capable of having those inherent properties/characteristic, since a product/composition and its properties cannot be separated. Carbopol is also used in the blend of polymers (column 7, lines 38-43) meeting claim 14. Cross-linked carboxymethylcellulose and sodium starch glycolate (column 8, lines 15-20) meet the limitations of claims 49 and 63. The composition of Bai would inherently have the property of zero order kinetics where the

release is not dependent on the concentration of the agent so that Bai meets the limitation of claim 67. Thus, Bai meets the limitations of the designated claims.

Response to Arguments

7. Applicant's arguments filed 09/06/07 have been fully considered but they are not persuasive.

Applicant says that Bai does not teach a dosage form that comprises homogeneous mixture of pharmacologically active substance and a hydrostatic couple, but as described above, Bai discloses hydrostatic couple in the form of mixture or dextran and cross-linked polyvinylpyrrolidone and a capsule or tablet is the dosage form, with the tablet meeting that requirements for a compressed product. Tablets and capsules are dosage forms that are orally administrable. Therefore, the designated claims are not allowable over Bai.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 47-58 and 61-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rork et al. (US 5,582,838) in view of Conte et al. (US 5,780,057).

Rork discloses a tablet formulation (column 7, lines 21-42) comprising pharmaceutically active ingredients such as antimicrobials, local anesthetic, analgesics and anti-inflammatory agents (column 6, lines 18, 20, 24 and 18), excipients such as lactose, magnesium stearate, polyvinylpyrrolidone and dyes (column 8, lines 13-25), CARBOPOL polymer (column 8, lines 45-65) and carbonate (claims 10). See also column 13, line 20 to column 14, line 9. The compressed tablet (Example 2) can also be filled into gelatin capsule (column 14, lines 8-10) meeting the capsule of claims 61, 68 and 70. The combination of the CARBOPOL and the polyvinylpyrrolidone constitutes the hydrostatic couple of the instant application and meets claims 47, 54, 56, 61, 68 and 70. The carbonate is the carbon dioxide precursor of claims 57, 58, 71 and 72 and also meeting the requirements for an expansion source in claims 56 and 70. Rork teaches particulate formulation (column 8, lines 21-25) and the pharmaceutically active agents are present in amounts of from about 0.01% to about 75% of the core weight (column 8, lines 26-32). Rork does not disclose cross-linked polyvinylpyrrolidone or cross-linked polyglucan. Ranitidine is one of the active agents in Rork (column 6, line 55). Conte discloses ranitidine composition that contains cross-linked polyvinylpyrrolidone (Example 4) or amylose or cross-linked amylase (column 6, lines17 and 18; column 7, line 40).

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). In the instant case, Conte and Rork disclose ranitidine containing composition. Therefore, it would have been obvious to on of ordinary skill in the art at the time the invention

was made to prepare the ranitidine composition of Rork. One having ordinary skill in the art would have been motivated to prepare a third composition comprising ranitidine, cross-linked polyvinylpyrrolidone, polyvinylpyrrolidone and carbopol with the expectation that this third composition when administered would function as ranitidine dosage form for inhibiting gastric ulcer secretion in ulcer patients. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Response to Arguments

10. Applicant's arguments filed 09/06/07 have been fully considered but they are not persuasive.

Applicant states that the multilayered dosage forms of Rork and Conte do not disclose or suggest dosage forms that include compressed homogeneous mixture of a drug and hydrostatic couple.

Response:

Both Rork and Conte teach tablet oral formulation. The multilayered tablet or the capsule form meets the compressed dosage form. When the two compositions are mixed, the composition of each layer is a mixture and the mixture would be homogeneous before the layered structure is formed. It is noted that the claimed dosage form, which is a tablet does not exclude layered tablets.

11. Claims 47 and 50-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dresdner, Jr. et al. (US 5,357,636) in view of Robinson et al. (US 6,071,539).

Dresdner is described above as anticipating claims 47, 50-53 and 56-60. While Dresdner discloses the claimed composition, that is, composition that contains active agent and hydrostatic couple, Dresdner uses glove as delivery vehicle for the composition. Dresdner does not deliver the composition in the form of capsule as recited in claims 61, 68 and 70. However, antimicrobial or antiseptic compositions such as the composition described by Dresdner can be formulated as tablet or capsule. Robinson describes formulation containing alkaline agent such as carbon dioxide precursor, oxygen precursor and chlorine dioxide precursor (column 4, lines 23-38) and therapeutic agent such as antibacterial agents, antihistamines, antifungal and antimicrobial agent (column 10, lines 45-66) in tablet or capsule form (column 10, line 25). Therefore, as it regard claims 61, 68, 70 and the claims dependent therefrom, it would have been obvious for the person of ordinary skill in the art to formulate the composition of Dresdner into known dosage forms of tablet or capsule and as taught by Robinson.

NO claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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